

### **REMARKS**

Reconsideration and removal of the grounds for rejection are respectfully requested. Claims 1, 3-6, 8, 9, 12-14, 16, 17, and 20-27 were in the application, claims 1 and 3 have been amended.

Claims 1 and 3 have been amended for clarity, to designate the sterilization step as step "f".

Claims 1, 3-6, 8-9, 12-14, 16-17 and 20-27 were rejected as being obvious over Davey et al, Laugharn, Jr. (U.S. Patent no. 6,270,723), Rooks et al, U.S. Patent Publication 2004/0265451, Bracco et al, U.S. Patent no. 4,352,746, and Shibantai et al, U.S. Patent no. 4,732,759.

In conducting an obviousness analysis, "[a] fact finder should be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning." KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1742, 167 L. Ed. 2d 705 (2007). This is because the genius of invention is often a combination of known elements that in hindsight seems preordained. In re Omeprazole Patent Litig., No. MDL 1291, 490 F. Supp. 2d 381, 2007 U.S. Dist. LEXIS 39670, at 400-01 (S.D.N.Y. May 31, 2007) (citation omitted) (quoting KSR, 127 S.Ct. at 1742); see also Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138 (Fed. Cir. 1985), Raytheon Co. v. Roper Corp., 724 F.2d 951, 961 (Fed. Cir. 1983) (stating that "virtually every claimed invention is a combination of old elements").

The Court in KSR also wrote, "[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." KSR Int'l

Co. v. Teleflex Inc., 127 S.Ct. 1727, 1741, 167 L. Ed. 2d 705 (2007) ("To facilitate review, this analysis should be made explicit.") (citing Kahn, 441 F.3d at 988... "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006).

If the prior art teaches away from combining known elements in the manner claimed by the invention at issue, discovering a successful way to combine them is less likely to be obvious. See KSR Int'l, 127 S. Ct. at 1740, 1745.

Amended claims 1 and 3 are not believed to be obvious over the cited references.

The Examiner admits that none of the references teaches the process claimed by the applicant, and points to nothing which would lead one skilled in the art to the applicants invention, and instead engages in a classic hindsight reconstruction to arrive at the applicants invention.

The Examiner states "upon noticing that the plant material is not consistently grinded, it is reasonable to repeat the process....". Yet, this bears no relationship to the presently claimed invention.

By its terms, claims 1 and 3 distinctly separate the final sterilization cycles to the point after grinding has finished, and there is no further grinding carried out.

Following the examiners' speculative reasoning, there would only be a subsequent freezing, a grinding, and then a thawing...Where is the final fast freeze/fast thaw step?

None of the references teach, suggest or even hint that one or more such fast freeze cycles should be performed after a material has been frozen, ground, and separated into

liquid and solid fractions, those separated fractions subject to the one or more cycles, as opposed to the raw material first processed.

Not only is there no disclosure of the claimed invention, each of the cited references clearly lead one away from the present invention, as none of the references consider such a final sterilization step to be necessary.

Davey et al teaches pulverizing plant tissue in liquid nitrogen for an extraction using 3% metaphosphoric acid. There is nothing to teach a method for obtaining a sterilized liquid fraction, and a sterilized solid plant residue and one skilled in the art would find nothing in this reference to lead them to the applicants invention.

Laugharn, Jr. leads one away by stating that the "the traditional freeze thaw sterilization" methods were not satisfactory, and where it was also clearly stated: "Lethality is correlated with slow freezing and rapid thawing." and further:

"Traditional freeze-thaw methods are limited in the speed of the freeze-thaw cycle by the time needed to transfer heat to and from the center of the sample to effect phase changes. The equilibrium rate is particularly slow in the case of large volume samples (e.g., about 100 ml or larger). Sterilization efficiency of the traditional methods is limited by the impracticality of performing a large number of freeze-thaw cycles by those methods.

Laugharn clearly leads one away from the proposed combination, instructing that slow freezing is necessary for sterilization, and rather this patent leads one to use of a "cryobaric sterilization" process where:

" ....biological and non-biological materials can be sterilized, decontaminated, or disinfected by repeatedly cycling between relatively high and low pressures. Pressure cycling can be carried out at low, ambient, or elevated temperatures (e.g., from about -40.degree. C. to about 95.degree. C.)." (Emphasis added)

Thus, one skilled in the art is lead away from the fast freeze/fast thaw sterilization discussed in the applicants' invention, and to a process where pressure, not temperature, is cycled, and this can even be undertaken at elevated temperatures which would clearly degrade the temperature sensitive components which are sought to be preserved according to the applicants' invention.

Note that consistent with Laugharn, the "quick freeze" in Davey had nothing to do with sterilization. There was only one freeze done to make the sample solid so it could be pulverized and then subjected to chemical extraction.

Rooks only teaches, again, numerous separations performed before a remainder is frozen and then once frozen, this material is pulverized so as to produce a powder for use in making various products. Rooks uses freezing for grinding purposes, and has no sterilizing step.

Bracco et al teaches grinding and extraction with solids, again with no sterilizing step.

Shibani et al teaches medicinal herbs used in cosmetics produced by a freeze separation process, again with no sterilization step.

The applicants invention first subjects a plant material to a fast freeze, then the plant material is crushed, defrosted and separated into two fractions, a liquid fraction, and a solid plant residue, then, each of these separated fractions are further subject to one or more fast freeze/fast thaw cold sterilization cycles. No such process is taught or suggested by the cited patents, and instead, one skilled in the art is led away from the applicants' invention.

Speculation by the examiner of further freeze cycles is a clear hindsight reconstruction, and contrary to the decision in KSR. Moreover, there is nothing which establishes the results of the applicants invention as being a predictable result based on a fair reading of these patents...rather, the opposite is true, as these patents clearly indicate to one skilled in the art that such an additional step is unnecessary.

The applicant also objects to the form of the rejection. Setting out a listing of patents which does not set out the primary reference nor discuss how the references were viewed in combination so as to arrive at the applicants invention, is believed improper and contrary to KSR where it was stated that the basis for rejection must be explicit:

"[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1741, 167 L. Ed. 2d 705 (2007) ("To facilitate review, this analysis should be made explicit.")

Based on the above amendments and remarks, favorable consideration and allowance of the application are respectfully requested.

Respectfully submitted,

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